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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,297

06/26/2006

Tsuyoshi Tada

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OLIFF & BERRIDGE, PLC
P.O. BOX 320850
ALEXANDRIA, VA 22320-4850

EXAMINER

MACFARLANE, STACEY NEE

ART UNIT

PAPER NUMBER

1649

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,297	Applicant(s) TADA ET AL.	
	Examiner STACEY MACFARLANE	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/22/2006;11/17/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claim 1 has been amended, claims 3 and 4 have been canceled, and claims 5-7 have been newly added, as requested in the amendment filed on October 20, 2008. Following the amendment, claims 1 and 5-7 are pending in the instant application.

Election/Restrictions

2. Applicant's election of Group I, drawn to a method of treating hydrocephalus in an animal or human comprising administering intraventricularly a pharmaceutical composition comprising HGF to an animal or human in need thereof, in the reply filed on October 20, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 2 and 5-7 are under examination in the instant office action.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 2 and 5-7 rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuzuki et al., *Acta Neurochirurgica Supplement*, 76:311-316, 2000, further in view of Fukumizu et al., *Pediatric Neurology*, 13(3):230-234, published October 1995.

Claims 1, 2 and 5-7 are drawn to a method of treating hydrocephalus in an animal or a human comprising administering intraventricularly a pharmaceutical composition comprising hepatocyte growth factor (HGF) to an animal or human in need thereof; wherein the HGF is human recombinant HGF; wherein the pharmaceutical composition further comprises a pharmaceutically acceptable carrier; wherein the pharmaceutically acceptable carrier is at least one selected from the group consisting of a carrier material, diluent, excipient, wetting agent, buffering agent, suspending agent, lubricating agent, adjuvant, vehicle, and material for delivery system; and wherein the pharmaceutically acceptable carrier is a carrier material for administration via cerebrospinal fluid (CSF).

The Tsuzuki et al. prior art teaches a method comprising intraventricular administration of HGF to rats for the treatment of ischemia and conclude that HGF has a profound neuroprotective effect against post ischemic neuronal death and may have

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implications for the development of therapeutic strategies for ischemic neuronal damage in humans.

The Tsuzuki et al. prior art does not teach administration of HGF for hydrocephalus. The Fukumizu et al. reference, however, teaches that it was well-recognized within the art that hypoxic/ischemic factors contribute and often cause the neuropathology of hydrocephalus (page 230).

It would have been obvious to one of ordinary skill in the art to use the method comprising intraventricular administration of HGF for the treatment of ischemic pathology in patients in need of treatment for ischemia associated with hydrocephalus. A skilled artisan would be motivated to combine the teachings of the prior art because Tsuzuki teaches that HGF treats ischemia and Fukumizu et al. teach that ischemic factors often cause neuropathologic sequelae with hydrocephalus. In *KSR International Co. v. Teleflex, Inc.*, the Supreme Court has stated that combining prior art elements according to known methods to yield predictable results is *prima facie* obvious if the following rationale can be applied:

- (1) the prior art includes each element claimed though not necessarily in the same reference.
- (2) it was within the technical grasp of one of ordinary skill in the art to combine the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately.
- (3) one of ordinary skill in the art would have recognized that the results of such combination were predictable.

(*KSR International Co. v. Teleflex, Inc.* 127 S. Ct. 1727, 82 USPQ2d 1385, Supreme Court, April 30, 2007).

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Based on the guidance and direction within the prior art references, a combination of the teachings would have been well within the technical grasp of a skilled artisan. Since each of the elements, (intraventricular administration of HGF for the successful treatment of ischemia; and the contribution of ischemia to the neuropathology of hydrocephalus), are functioning as they would separately, then one of ordinary skill in the art would have been able to predictably combine the elements with a reasonable expectation of success. Therefore, the invention as a whole is *prima facie obvious*, if not actually anticipated by the reference.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-W and ALT F 5:30 to 3:30, TELEWORK-Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/John D. Ulm/
Primary Examiner, Art Unit 1649